

## **EXHIBIT G**

Vladeck, Ph.D., Bruce C.

May 4, 2007

New York, NY

Page 1

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

-----X MDL NO. 1456

IN RE: PHARMACEUTICAL INDUSTRY : CIVIL ACTION:

AVERAGE WHOLESALE PRICE LITIGATION : 01-CV-12257-PBS

-----X

THIS DOCUMENT RELATES TO: :

U.S. ex rel. Ven-A-Care of the : CIVIL ACTION:

Florida Keys, Inc. v. Abbott : 06-CV-11337-PBS

Laboratories, Inc. :

-----X

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

-----X

STATE OF ALABAMA, : CASE NO.

Plaintiff, : CV-05-219

v. :

ABBOTT LABORATORIES, INC., : JUDGE

et al., : CHARLES PRICE

Defendants. :

-----X

Henderson Legal Services  
202-220-4158

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vladeck, Ph.D., Bruce C.

May 4, 2007

New York, NY

Page 2

1 STATE OF WISCONSIN CIRCUIT COURT DANE COUNTY  
 2 -----X  
 3 STATE OF WISCONSIN, : CASE NO.  
 4 Plaintiff, : 04-CV-1709  
 5 v. :  
 6 AMGEN INC., et al., :  
 7 Defendants. :  
 8 -----X  
 9  
 10 IN THE COURT OF COMMON PLEAS  
 11 FIFTH JUDICIAL CIRCUIT  
 12 -----X  
 13 STATE OF SOUTH CAROLINA, and : STATE OF  
 14 HENRY D. McMASTER, in his official : SOUTH CAROLINA  
 15 capacity as Attorney General for : COUNTY OF  
 16 the State of South Carolina, : RICHLAND  
 17 Plaintiff, :  
 18 v. : CIVIL ACTION:  
 19 MYLAN LABORATORIES, INC. : 07-CP-40-0283  
 20 Defendant. :  
 21 -----X  
 22

Page 3

1 IN THE COURT OF THE SECOND JUDICIAL CIRCUIT  
 2 IN AND FOR LEON COUNTY, FLORIDA  
 3 THE STATE OF FLORIDA  
 4 ex rel.  
 5 -----X  
 6 VEN-A-CARE OF THE FLORIDA :  
 7 KEYS, INC., a Florida :  
 8 Corporation, by and through its :  
 9 principal officers and directors, :  
 10 ZACHARY T. BENTLEY and :  
 11 T. MARK JONES, :  
 12 Plaintiffs, :  
 13 vs. : Civil Action  
 14 MYLAN LABORATORIES, INC.; MYLAN : No.: 98-3032G  
 15 PHARMACEUTICALS INC.; NOVOPHARM : Judge:  
 16 LTD., SCHEIN PHARMACEUTICAL, INC.; : William L.  
 17 TEVA PHARMACEUTICAL INDUSTRIES : Gary  
 18 LTD., TEVA PHARMACEUTICAL USA; :  
 19 and WATSON PHARMACEUTICALS, INC. :  
 20 Defendants. :  
 21 -----X  
 22

Page 4

1 IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS  
 2 STATE OF MISSOURI  
 3 -----X  
 4 STATE OF MISSOURI, ex rel., :  
 5 JEREMIAH W. (JAY) NIXON, :  
 6 Attorney General, :  
 7 and :  
 8 MISSOURI DEPARTMENT OF SOCIAL :  
 9 SERVICES, DIVISION OF MEDICAL : Case No.:  
 10 SERVICES, : 054-1216  
 11 Plaintiffs, : Division  
 12 : No. 31  
 13 vs. :  
 14 DEY INC., DEY, L.P., MERCK KGaA, :  
 15 EMD, INC., WARRICK :  
 16 PHARMACEUTICALS CORPORATION, :  
 17 SCHERING-PLOUGH CORPORATION, and :  
 18 SCHERING CORPORATION, :  
 19 Defendants. :  
 20 -----X  
 21  
 22

Page 5

1 New York, New York  
 2 Friday, May 4, 2007  
 3  
 4  
 5 Videotaped Deposition of BRUCE C.  
 6 VLADECK, Ph.D., a witness herein, called for  
 7 examination by counsel for Abbott Laboratories in  
 8 the above-entitled matter, pursuant to Subpoena,  
 9 the witness being duly sworn by JOMANNA DEROSA, a  
 10 Notary Public in and for New York, taken at the  
 11 offices of Jones Day, 222 East 41st Street, New  
 12 York, New York, at 8:38 a.m. on Friday, May 4,  
 13 2007, and the proceedings being taken down by  
 14 Stenotype by JOMANNA DEROSA, and transcribed under  
 15 her direction.  
 16  
 17  
 18  
 19  
 20  
 21  
 22

2 (Pages 2 to 5)

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Vladeck, Ph.D., Bruce C.

May 4, 2007

New York, NY

Page 262	Page 264
<p>1 principle liaison with OIG. So, it probably  2 would have been that official plus people from  3 some of the other parts of the agency that had  4 particular concerns or particular agenda issues  5 or things of that sort. Undoubtedly, someone  6 from our financial management office as well  7 would have participated.</p> <p>8 Q. And who was the director of the Office  9 for Program Integrity?</p> <p>10 A. The first director was Judith Berik.  11 She was director from '94 through mid-to late  12 '96. I believe he was succeeded by Linda Ruiz.</p> <p>13 MS. BROOKER: How do you spell that  14 last name?</p> <p>15 THE WITNESS: Berik is B-E-R-I-K. Ruiz  16 is R-U-I-Z.</p> <p>17 A. I think that was it during my tenure.</p> <p>18 Q. We have a number of letters that I  19 would like to show that were addressed to you  20 from Ven-A-Care. Before pulling them out --  21 well, let me pull them out and put them in front  22 of you so you can recall them.</p>	<p>1 163.</p> <p>2 Q. And I'll hand all of those to Dr.  3 Vladeck and ask you to take a quick look.</p> <p>4 A. Thank you. This document is dated June  5 12th with a cover sheet to the Inspector General.  6 I don't have a number on it.</p> <p>7 MS. BROOKER: We don't have a June 12th  8 one.</p> <p>9 MR. COOK: I'm sorry. It's at the top.  10 It's been previously marked as Exhibit Abbott  11 017, a June 12, 1997, letter from Bruce Vladeck  12 to Ven-A-Care, with a cover fax sheet from Zach  13 Bentley and Mark Jones to June Gibbs Brown.</p> <p>14 Q. Dr. Vladeck, I would like to turn first  15 to the October 2, 1996 letter. It's with the  16 large exhibit, and it's marked Exhibit Abbott  17 160. And I'm going to focus just on the first  18 few pages of that very large exhibit, which is  19 the actual letter from Zach Bentley and Mark  20 Jones at Ven-A-Care to you on October 2, 1996.</p> <p>21 First, have you ever seen this letter  22 before?</p>
Page 263	Page 265
<p>1 The first is very lengthy, and I  2 apologize, but we're only going to be talking  3 about the first few pages of this very lengthy  4 document. And so this will be Exhibit Abbott  5 160. I'll ask the court reporter to mark that and  6 hand it to you.</p> <p>7 (Exhibit Abbott 160, Exhibit  8 Abbott 161, Exhibit Abbott 162, and Exhibit  9 Abbott 163 marked for identification.)</p> <p>10 (Discussion off the record.)</p> <p>11 MR. COOK: For the record, we'll put  12 the following exhibits and then I'll hand them to  13 Dr. Vladeck. First is an October 2nd, 1996,  14 letter from Ven-A-Care to Dr. Vladeck. Its  15 Exhibit Abbott 160. The second is a December 3,  16 1996, letter from Ven-A-Care to Thomas Hoyer.  17 It's numbered Exhibit Abbott 161.</p> <p>18 August 13, 1997, letter from --  19 addressed to Dr. Vladeck from Ven-A-Care. Its  20 Exhibit Abbott 162.</p> <p>21 Next is a July 10, 1997, letter from  22 Ven-A-Care to Dr. Vladeck. It's Exhibit Abbott</p>	<p>1 A. I have.</p> <p>2 Q. When do you recall first seeing this  3 letter?</p> <p>4 A. I -- I honestly don't recall whether I  5 saw it in -- in '96. I may have. I'm certain I  6 saw it when I was engaged by Mr. Azorsky in 2003.  7 I've seen it on a number of occasions since, but  8 during that time I tried to remember whether I  9 saw it in '96 and I -- I'm not certain one way or  10 another.</p> <p>11 Q. If you did not see it in October --  12 whether or not you saw it in October of 1996,  13 what would have been the typical process for  14 handling this sort of correspondence coming in to  15 you as administrator of HCFA?</p> <p>16 A. I'm not sure this would have received  17 the typical process because of the heading at the  18 top that it was sensitive and under court seal  19 and so forth. It might, therefore, have been  20 routed in the first instance to counsel's office.  21 Had it not been, it would have probably been  22 routed to the Department of Integrity Office by</p>

67 (Pages 262 to 265)

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Vladeck, Ph.D., Bruce C.

May 4, 2007

New York, NY

Page 266

Page 268

1 the agency's executive secretary to prepare a  
 2 response for my signature or something of that  
 3 sort.

4 Q. How would we go about determining, 11  
 5 years later, how this document and its contents  
 6 were circulated within HCFA in 1996?

7 MS. BROOKER: Objection. Form.

8 A. If there were ever a response received  
 9 from anywhere in the agency, a written response  
 10 by Ven-A-Care, one could track the letter back  
 11 through a correspondence file. If there was no  
 12 follow-up I think one would have to work  
 13 backwards from the correspondence and associated  
 14 -- documents associated with it as they made  
 15 their way through the agency.

16 Q. And so, to the extent that there was a  
 17 response, there would be a way from tracking from  
 18 the response to the documents supporting that  
 19 response?

20 MS. BROOKER: Objection, form.

21 A. There should be.

22 Q. Was that your understanding of how

1 when it says the administrator referred the  
 2 letter to Ms. Buto and payment policy is one of  
 3 her areas of responsibility, would that be  
 4 consistent with your regular practice and  
 5 procedure of handling correspondence such as  
 6 this?

7 A. Again, I wouldn't have personally done  
 8 that but, yes, that would have made its way to  
 9 Kathy, yes.

10 Q. And to the extent that someone within  
 11 HCFA was to be put on notice of facts contained  
 12 within the correspondence from Ven-A-Care, is it  
 13 fair to say that Ms. Buto is the one person most  
 14 responsible for Medicare drug payment policy at  
 15 this time within HCFA?

16 A. Yes, it would be.

17 Q. The letter from Ven-A-Care dated  
 18 October 2, 1996, ends with Mr. Bentley and Mr.  
 19 Jones stating that they would be happy to meet  
 20 with you and answer any questions or concerns  
 21 about the issues raised in the letter? Did you  
 22 ever meet with Mr. Jones or Mr. Bentley?

Page 267

Page 269

1 correspondence was kept at HCFA?

2 A. To the extent there was a response,  
 3 there should be a way of working backwards from  
 4 that to the initial incoming document and the  
 5 intermediate documents generated in the process  
 6 of preparing a response.

7 MR. COOK: I'll ask the court reporter  
 8 to mark as Exhibit Abbott 164.

9 (Exhibit Abbott 164 marked for  
 10 identification.)

11 Q. Could you take a look at that and tell  
 12 me if you've seen that document before?

13 A. No, I don't believe so.

14 MR. COOK: For the record, this is a  
 15 December 17, 1996, letter from Kathleen Buto to  
 16 T. Mark Jones of Ven-A-Care of the Florida Keys.

17 Q. Does this appear to be the response  
 18 from Kathleen Buto to Mr. Jones following the  
 19 October 2, 1996, letter to you?

20 MS. BROOKER: Objection, form.

21 A. It would appear to be that, yes.

22 Q. And at the end of the first paragraph

1 A. No, I don't believe so.

2 Q. The letter begins at the beginning of  
 3 Exhibit Abbott 160 that Ven-A-Care of the Florida  
 4 Keys -- and it reads:

5 "Has attempted for more than seven  
 6 years to assist the health care financing  
 7 administration" -- regarding the issues in that  
 8 letter.

9 Do you know what, if anything, Ven-A-  
 10 Care did for seven years prior to 1996?

11 MS. BROOKER: Objection, form.

12 A. Again, other than some of the earlier  
 13 activities described in the letter itself, I had  
 14 no independent knowledge of anything about Ven-A-  
 15 Care.

16 MR. BREEN: I was not looking at the  
 17 document. I want to pose a form objection to the  
 18 last question and response now that I've looked  
 19 at what you're referring to as an exhibit.

20 Q. The second page of the letter lists a  
 21 number of Office of Inspector General reports. Do  
 22 you recall you and I looked at a report from 1992

68 (Pages 266 to 269)

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Vladeck, Ph.D., Bruce C.

May 4, 2007

New York, NY

Page 270	Page 272
<p>1 that talked about the invoice price of vancomycin  2 by dialysis providers?  3     A. Yes, we did.  4     Q. Can you tell me, does it appear that  5 that particular OIG report is not listed by Ven-  6 A-Care in the OIG reports that it enumerates  7 there for you?  8     MS. BROOKER: Objection to form.  9     A. The list of IG reports on Page 2 does  10 not contain the report we were discussing about  11 earlier -- discussing earlier.  12     Q. In the paragraph that follows, the  13 letter-writers from Ven-A-Care state in this  14 letter to you -- and I'll read it:  15         "Over a year ago we traveled to the  16 HCFA in Baltimore and made a detailed  17 presentation regarding these excessive  18 reimbursements and their impact on the health  19 care delivery system."  20     Do you know anything about whether Ven-  21 A-Care made a trip to Baltimore and met with HCFA  22 officials?</p>	<p>1 paragraph reads:  2         "Our company has been solicited on  3 numerous occasions by drug manufacturers who brag  4 about their use of falsely inflated pricing  5 information as a reason for purchasing their  6 product over a competitor with a lower AWP."  7         First of all, do you have any idea  8 whether or not Ven-A-Care's allegation here is  9 true?  10     MS. BROOKER: Objection to form.  11     A. I have no independent information about  12 that.  13     Q. But you would agree with me that as of  14 October 2, 1996, Kathleen Buto at least was aware  15 that that was an allegation that Ven-A-Care was  16 making.  17     A. I would say that whoever in the agency  18 actually read this letter and looked at the  19 material would have been aware of the allegation,  20 yes.  21     MR. COOK: And then the next letter, in  22 terms of sequencing of date, is Exhibit Abbott</p>
Page 271	Page 273
<p>1     A. Other than the assertion in the letter,  2 that's all I know.  3     Q. So you don't recall ever talking to  4 anybody within HCFA about meetings with Ven-A-  5 Care in approximately 1995?  6     A. No, I don't.  7     Q. The next sentence asserts that:  8         "No meaningful action has been either  9 proposed or implemented by your agency to deal  10 with these issues."  11     Would you agree that as of October of  12 1996 no meaningful action had been proposed or  13 implemented by HCFA --  14     MS. BROOKER: Objection.  15     Q. -- to deal with the issues described in  16 this letter?  17     MR. BREEN: Objection, form.  18     A. I would not agree. Again, we had  19 proposed to change the Medicare Part B drug  20 pricing methodology.  21     Q. On Page 5 of the letter in the second  22 paragraph, the last sentence of the second</p>	<p>1 161, which is a December 3 letter to Thomas  2 Hoyer, H-O-Y-E-R, Office of Chronic Care and  3 Insurance Policy. And it's marked Exhibit Abbott  4 161.  5     Q. Do you recognize that, Mr. Vladeck?  6     A. No, I don't. I don't believe I've seen  7 it before today.  8     Q. Who is Tomas Hoyer?  9     A. Tom was the director, again, in charge  10 of essentially Medicare reimbursement for  11 everything other, but hospitals and physician.  12     Q. So Thomas Hoyer would be responsible  13 for reimbursement for infusion therapy, for  14 example?  15     A. He was certainly responsible for home  16 care and DME reimbursement policies.  17     Q. The next letter in -- going again date  18 sequence is, I believe -- tell me if I'm wrong --  19 what we've previously marked as Exhibit Abbott  20 017, a June 12, 1997, letter to you?  21     A. Yes.  22     Q. Do you recall that letter, Dr. Vladeck?</p>

69 (Pages 270 to 273)

Henderson Legal Services  
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Vladeck, Ph.D., Bruce C. - Vol. II  
New York, NY

June 21, 2007

Page 285

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

-----X MDL NO. 1456  
IN RE: PHARMACEUTICAL INDUSTRY : CIVIL ACTION:  
AVERAGE WHOLESALE PRICE LITIGATION : 01-CV-12257-PBS

-----X  
THIS DOCUMENT RELATES TO: :  
U.S. ex rel. Ven-A-Care of the : CIVIL ACTION:  
Florida Keys, Inc. v. Abbott : 06-CV-11337-PBS  
Laboratories, Inc. :  
-----X

IN THE CIRCUIT COURT OF  
MONTGOMERY COUNTY, ALABAMA

-----X  
STATE OF ALABAMA, : CASE NO.  
Plaintiff, : CV-05-219  
v. :  
ABBOTT LABORATORIES, INC., : JUDGE  
et al., : CHARLES PRICE  
Defendants. :  
-----X

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Vladeck, Ph.D., Bruce C. - Vol. II  
 New York, NY

June 21, 2007

Page 286		Page 288
1 STATE OF WISCONSIN	CIRCUIT COURT DANE COUNTY	1 IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
2 -----X		2 STATE OF MISSOURI
3 STATE OF WISCONSIN,	CASE NO.	3 -----X
4 Plaintiff,	: 04-CV-1709	4 STATE OF MISSOURI, ex rel.,
5 v.		5 JEREMIAH W. (JAY) NIXON,
6 AMGEN INC., et al.,	:	6 Attorney General,
7 Defendants.	:	7 and
8 -----X		8 MISSOURI DEPARTMENT OF SOCIAL
9		9 SERVICES, DIVISION OF MEDICAL : Case No.:
10 IN THE COURT OF COMMON PLEAS		10 SERVICES, : 054-1216
11 FIFTH JUDICIAL CIRCUIT		11 Plaintiffs, : Division
12 -----X		12 : No. 31
13 STATE OF SOUTH CAROLINA, and	: STATE OF	13 vs. :
14 HENRY D. McMASTER, in his official	: SOUTH CAROLINA	14 DEY INC., DEY, L.P., MERCK KGaA, :
15 capacity as Attorney General for	: COUNTY OF	15 EMD, INC., WARRICK :
16 the State of South Carolina,	: RICHLAND	16 PHARMACEUTICALS CORPORATION, :
17 Plaintiff,	:	17 SCHERING-PLough CORPORATION, and :
18 v.	: CIVIL ACTION:	18 SCHERING CORPORATION, :
19 MYLAN LABORATORIES, INC.	: 07-CP-40-0283	19 Defendants.
20 Defendant.	:	20 -----X
21 -----X		21
22		22
Page 287		Page 289
1 IN THE COURT OF THE SECOND JUDICIAL CIRCUIT		1 New York, New York
2 IN AND FOR LEON COUNTY, FLORIDA		2 Thursday, June 21, 2007
3 THE STATE OF FLORIDA		3
4 ex rel.		4 CONTINUED Videotaped Deposition of
5 -----X		5 BRUCE C. VLADECK, Ph.D., a witness herein, called
6 VEN-A-CARE OF THE FLORIDA	:	6 for examination by counsel for Abbott Laboratories
7 KEYS, INC., a Florida	:	7 in the above-entitled matter, pursuant to
8 Corporation, by and through its	:	8 Subpoena, the witness being duly sworn by JOMANNA
9 principal officers and directors,	:	9 DEROSA, a Notary Public in and for New York, taken
10 ZACHARY T. BENTLEY and	:	10 at the offices of Jones Day, 222 East 41st Street,
11 T. MARK JONES,	:	11 New York, New York, at 8:54 a.m. on Thursday, June
12 Plaintiffs,	:	12 21, 2007, and the proceedings being taken down by
13 vs.	: Civil Action	13 Stenotype by JOMANNA DEROSA, and transcribed under
14 MYLAN LABORATORIES, INC.; MYLAN	: No.: 98-3032G	14 her direction.
15 PHARMACEUTICALS INC.; NOVOPHARM	: Judge:	15
16 LTD., SCHEIN PHARMACEUTICAL, INC.;	: William L.	16
17 TEVA PHARMACEUTICAL INDUSTRIES	: Gary	17
18 LTD., TEVA PHARMACEUTICAL USA;	:	18
19 and WATSON PHARMACEUTICALS, INC.	:	19
20 Defendants.	:	20
21 -----X		21
22		22

2 (Pages 286 to 289)

Henderson Legal Services  
 202-220-4158

Vladeck, Ph.D., Bruce C. - Vol. II

June 21, 2007

New York, NY

Page 570	Page 572
<p>1 form. Leading. I don't think you're allowed to 2 lead that witness.</p> <p>3 THE WITNESS: We're having an audio 4 problem.</p> <p>5 THE VIDEOGRAPHER: The time is 4:03 6 p.m. We're going off the record with Tape No. 10. 7 (Off the record discussion.)</p> <p>8 THE VIDEOGRAPHER: It's 4:03 p.m. 9 We're going back on the record, continuing with 10 Tape No. 10.</p> <p>11 (The last question was read 12 back by the reporter.)</p> <p>13 A. I would --</p> <p>14 MR. MC DONALD: Objection to form.</p> <p>15 A. I would sort of restate it more 16 generally. I think the whole of the Medicare 17 program is predicated on the -- 18 (Teleconference static.)</p> <p>19 THE WITNESS: It seems to be when I 20 talk we get the interference.</p> <p>21 A. The whole program is predicated on 22 a mutually trusting, honest, supportive</p>	<p>1 Q. Let me ask it to you this way: Did 2 you expect, as administrator of HCFA, that in 3 publishing AWPs that the manufacturers knew the 4 Medicare program would be relying on for 5 reimbursement, that they could make those AWPs 6 whatever they wanted to?</p> <p>7 MR. MC DONALD: Objection to form. 8 MR. GORTNER: Object to form. 9 MR. EDWARDS: Objection to form. 10 MR. ESCOBAR: Objection to form.</p> <p>11 A. I think there are two separate 12 questions there. One is we assumed that the 13 manufacturers knew that the prices published in 14 the Red Book or the AWP prices that were publicly 15 reported affected Medicare reimbursement. 16 Again, our presumption was that 17 they were not reported at the level they were or 18 set at the level they were solely to maximize 19 Medicare reimbursement.</p> <p>20 Q. So, as HCFA administrator you never 21 advised any drug manufacturers that it was okay 22 for them to use the difference between AWP and</p>
Page 571	Page 573
<p>1 relationship between providers and the program. 2 Q. Does that trust extend to 3 participants like drug manufacturers who publish 4 AWPs that they know the Medicare program is 5 relying on?</p> <p>6 MR. ESCOBAR: Objection to form. 7 MR. EDWARDS: Objection to form. 8 A. I would say actually the drug 9 manufacturers are in a somewhat different 10 relationship with the Medicare program than 11 providers who are reimbursed directly by Medicare, 12 because as a rule the manufacturers are not 13 reimbursed directly. 14 And so the relationship on the 15 Medicare side between drug manufacturers and the 16 agency prior to the enactment of Part D was one 17 step further removed than it was, say, with the 18 durable medical equipment suppliers or hospitals 19 or individual physicians.</p> <p>20 Again, on the Medicaid side there 21 was a very specific relationship with the 22 manufacturers provided under the rebate program.</p>	<p>1 acquisition price in order to influence purchase 2 of their products? 3 A. I don't believe I ever had any 4 direct conversations with drug manufacturers or 5 their representatives around those issues. 6 Q. Are you aware of anyone at HCFA 7 that authorized drug manufacturers to market their 8 drugs on the basis of the spread or the difference 9 between AWP and acquisition costs? 10 MR. ESCOBAR: Objection to form. 11 A. No, I'm not aware. 12 Q. Are you aware of anyone at HCFA who 13 told drug manufacturers that it was all right to 14 have physicians make prescribing decisions based 15 on the amount of money that they could make by 16 prescribing one manufacturer's drug over another? 17 A. I would have been very upset if I 18 had learned that anyone at HCFA had condoned such 19 behavior. 20 Q. And you have no knowledge that 21 anyone condoned that type behavior; did you? 22 A. I certainly have no knowledge, but</p>

73 (Pages 570 to 573)

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Vladeck, Ph.D., Bruce C. - Vol. II

June 21, 2007

New York, NY

Page 574	Page 576
<p>1 I couldn't entirely rule it out either, so.</p> <p>2 Q. In preparing to talk to you today I</p> <p>3 read one of your many articles that you've written</p> <p>4 about the Medicare program, and you make a comment</p> <p>5 in there that data from one to two years are not</p> <p>6 sufficiently accurate or a reliable source on</p> <p>7 which to base conclusions or major changes in</p> <p>8 public policy.</p> <p>9 Do you recall ever making that</p> <p>10 statement?</p> <p>11 A. I don't doubt it, but I -- I don't</p> <p>12 recall the context.</p> <p>13 Q. It was actually in a different</p> <p>14 context. It didn't relate to drug reimbursement.</p> <p>15 But what I wanted to ask you is whether you</p> <p>16 believe that that statement has any accuracy in</p> <p>17 the context of the reports that were published by</p> <p>18 OIG in connection with drug reimbursement?</p> <p>19 MR. ESCOBAR: Objection to form.</p> <p>20 MR. MC DONALD: Objection to form.</p> <p>21 MR. EDWARDS: Objection.</p> <p>22 A. If we're talking about the various</p>	<p>1 about some testimony that you gave in your first</p> <p>2 deposition where you described two separate</p> <p>3 discussions that you had had with drug</p> <p>4 manufacturers.</p> <p>5 Do you recall that testimony?</p> <p>6 A. Roughly, yes.</p> <p>7 Q. Just to refresh your recollection,</p> <p>8 you had testified that on two occasions you spoke</p> <p>9 with representatives of drug manufacturers. The</p> <p>10 first was in connection with a J&amp;J subsidiary who</p> <p>11 had a Medicaid rebate problem in about '96 or '97.</p> <p>12 Do you recall that testimony?</p> <p>13 MR. COHEN: Objection.</p> <p>14 A. That's correct, yes.</p> <p>15 Q. Do you recall who initiated that</p> <p>16 contact between yourself and the representative</p> <p>17 from the J&amp;J subsidiary?</p> <p>18 A. It would have been whoever the J&amp;J</p> <p>19 representative was.</p> <p>20 Q. And at the time you testified in</p> <p>21 your first deposition, I believe you didn't recall</p> <p>22 anything more specific about that conversation;</p>
<p>1 reports which have been exhibits in the -- during</p> <p>2 the course of this deposition on which I was asked</p> <p>3 to comment, I don't completely question the</p> <p>4 accuracy of any of the data reported by OIG or</p> <p>5 others. I do think in general that the link</p> <p>6 between a specific report of data and policy</p> <p>7 decisions is not always entirely straightforward</p> <p>8 and that there are lots of other considerations,</p> <p>9 one of which would be how limited or short term or</p> <p>10 whatever the data was.</p> <p>11 In the case of the drug pricing</p> <p>12 reports, many of which have been discussed in the</p> <p>13 course of this deposition, I was, frankly, less --</p> <p>14 to the extent I was paying attention at the time I</p> <p>15 was, frankly, less concerned with the accuracy of</p> <p>16 any particular number than by the recognition that</p> <p>17 we were highly constrained in our policies by the</p> <p>18 statutes which we had sought to change,</p> <p>19 unsuccessfully. So that whatever the right thing</p> <p>20 to do might be, we were not in a position to do</p> <p>21 it.</p> <p>22 Q. I wanted to turn next to asking you</p>	<p>1 did you?</p> <p>2 A. I -- I recalled that they described</p> <p>3 the problem as they had offered such a significant</p> <p>4 discount to state hospitals to maintain the market</p> <p>5 for Halcion that when the rebate was applied to</p> <p>6 other Medicaid -- the best-price provision was</p> <p>7 applied to other Medicaid purchases of the drug,</p> <p>8 they actually owed in rebates more than they had</p> <p>9 received in reimbursement for the drug. And they</p> <p>10 thought that was unfair and unreasonable.</p> <p>11 Q. Do you recall specifically who you</p> <p>12 spoke to in that conversation?</p> <p>13 A. No, I don't.</p> <p>14 Q. The second conversation you</p> <p>15 testified to was a conversation with a -- a</p> <p>16 lobbyist of a drug manufacturer that you couldn't</p> <p>17 remember who was trying to convince HCFA to cover</p> <p>18 an antiemetic drug.</p> <p>19 Do you recall that testimony?</p> <p>20 A. Yes.</p> <p>21 Q. Again, who would have initiated</p> <p>22 that contact?</p>
	Page 577

74 (Pages 574 to 577)

Henderson Legal Services  
202-220-4158

320d321f-596a-4e1f-8444-2c4e6f42d4ae

Vladeck, Ph.D., Bruce C. - Vol. II

June 21, 2007

New York, NY

Page 578	Page 580
<p>1       A. It would have been the lobbyist.</p> <p>2       Q. You don't recall specifically who</p> <p>3       you spoke to?</p> <p>4       A. Well, no, I do. I think it was a</p> <p>5       Fred Griffy.</p> <p>6       Q. Do you recall anything about the</p> <p>7       substance of the conversations with Mr. Griffy?</p> <p>8       A. Well, again, the -- his client had</p> <p>9       just received FDA approval for a new oral</p> <p>10      antiemetic drug. At the time Medicare covered,</p> <p>11      under Part B, outpatient cancer chemotherapeutic</p> <p>12      drugs, and he was trying to convince us that</p> <p>13      antiemetics could be covered under that provision.</p> <p>14      Q. And you said a single meeting with</p> <p>15      Mr. Griffy?</p> <p>16      A. There may have been two, because we</p> <p>17      did have staff look into the issue and look at</p> <p>18      some information they supplied. And there may --</p> <p>19      there was undoubtedly a second conversation after</p> <p>20      staff reported back on their analysis of it.</p> <p>21      Whether it was face-to-face or over the phone I</p> <p>22      don't recall.</p>	<p>1       that AWP inflation was because they were forced to</p> <p>2       compete with other drug manufacturers by raising</p> <p>3       their AWPs?</p> <p>4            MR. EDWARDS: Objection to form.</p> <p>5            MR. GORTNER: Objection to form.</p> <p>6       A. Not that I'm aware.</p> <p>7       Q. Did any drug manufacturer ever</p> <p>8       contact you and advise you that spread marketing</p> <p>9       was going on?</p> <p>10        MR. EDWARDS: Objection to form.</p> <p>11        MR. GORTNER: Objection to form.</p> <p>12       A. Not that I'm aware.</p> <p>13       MS. CONNOLLY: I don't have any</p> <p>14       further questions. Thank you for your time.</p> <p>15        THE VIDEOGRAPHER: The time is 4:15</p> <p>16       p.m. We're going off the record with Tape No. 10.</p> <p>17           (Recess taken.)</p> <p>18        THE VIDEOGRAPHER: The time is 4:25</p> <p>19       p.m., and we're going back on the record,</p> <p>20       continuing with Tape No. 10.</p> <p>21        MR. LORUSSO: My name is Mike</p> <p>22       Lorusso. I'm here on behalf of the Commonwealth</p>
Page 579	Page 581
<p>1       Q. And since testifying at your first</p> <p>2       deposition you don't recall any additional</p> <p>3       conversations you had with drug manufacturers</p> <p>4       while you were administrator of HCFA.</p> <p>5       A. No, I don't.</p> <p>6       Q. We talked a lot today with</p> <p>7       defendants' counsel and most recently with Mr.</p> <p>8       Edwards about efforts that HCFA may or may not</p> <p>9       have made to speak with drug manufacturers.</p> <p>10      Do you recall generally that</p> <p>11      testimony?</p> <p>12      A. Yes.</p> <p>13      Q. Were you ever contacted by any drug</p> <p>14      manufacturer at any time who, upon reviewing the</p> <p>15      OIG reports, sought to enlighten HCFA about the</p> <p>16      reasons that the OIG had found AWP inflation?</p> <p>17        MR. EDWARDS: Objection to form.</p> <p>18        MR. GORTNER: Objection to form.</p> <p>19        MR. ESCOBAR: Objection to form.</p> <p>20      A. Not that I recall.</p> <p>21      Q. Did any drug manufacturer ever</p> <p>22      contact you to let you know that the reason for</p>	<p>1       of Pennsylvania. I'd just like to say that we</p> <p>2       have questions for Dr. Vladeck on behalf of the</p> <p>3       Commonwealth. However, at this time we're unable</p> <p>4       to conduct our examination based on restrictions</p> <p>5       that have been placed on the use of our discovery</p> <p>6       documents by counsel for TAP. Therefore, we</p> <p>7       reserve the right to conduct our examination at</p> <p>8       such time as the dispute is resolved by the Court.</p> <p>9            MR. BREEN: Okay. Let's roll.</p> <p>10        MR. COOK: Just for a second, I</p> <p>11       have no idea what that means, but as a</p> <p>12       representative of the law firm representing TAP,</p> <p>13       just for the record, if you have any questions for</p> <p>14       the doctor, he's right there at the end of the</p> <p>15       table, and we would expect you to ask them. He</p> <p>16       can always be -- attempted to be brought back for</p> <p>17       more questions, but in the future if we try to use</p> <p>18       his testimony and you said that you didn't have a</p> <p>19       chance to ask questions, we're going to -- we're</p> <p>20       going to assert otherwise.</p> <p>21        MR. LORUSSO: Let me just say on</p> <p>22       the record that -- let me reiterate what I said.</p>

75 (Pages 578 to 581)

Henderson Legal Services  
202-220-4158

vladeck, Ph.D., Bruce C. - Vol. II

June 21, 2007

New York, NY

Page 582	Page 584
<p>1 The reason why I don't have -- the reason why I  2 cannot ask the particular questions that I would  3 like to ask Dr. Vladeck is based on restrictions  4 that have been put on us by TAP. So, with respect  5 to those particular questions I believe the  6 record's clear.</p> <p>7 MR. COOK: Since I don't know what  8 those questions are I don't know how clear it is,  9 but it is what it is.</p> <p>10 MR. BREEN: All right. Roll.</p> <p>11 MS. BROOKER: Let me just say in  12 response to all of that, the Government of the  13 United States reserves its right to respond to any  14 of those comments or objections, or whatever they  15 just were, at an appropriate time.</p> <p>16 MR. BREEN: Now can we roll?</p> <p>17</p> <p>18 EXAMINATION BY COUNSEL FOR  19 VEN-A-CARE</p> <p>20 BY MR. BREEN:</p> <p>21 Q. I just have a few questions, I  22 believe, Dr. Vladeck.</p>	<p>1 A. That's -- Yes.</p> <p>2 Q. All right. Now, when you were  3 testifying about confidentiality of pricing  4 information provided by the drug companies with  5 respect to the Medicaid rebate obligations, what  6 specific pricing information were you talking  7 about?</p> <p>8 MR. ESCOBAR: Objection to the  9 form.</p> <p>10 A. Well, I would include all the  11 pricing information that was provided by the  12 manufacturers to HCFA, which would include both  13 average manufacturing price and best price.</p> <p>14 Q. Okay.</p> <p>15 MR. BREEN: And what's wrong with  16 that question, counselor? I want to clean it up  17 if there's a problem.</p> <p>18 MR. ESCOBAR: I didn't understand  19 it.</p> <p>20 MR. BREEN: Okay.</p> <p>21 Q. What pricing information were you  22 aware that drug companies provided under their</p>
Page 583	Page 585
<p>1 A. Yes.</p> <p>2 Q. And you know I'm Jim Breen. I  3 represent Ven-A-Care of the Florida Keys.</p> <p>4 A. I'm aware, yes.</p> <p>5 Q. The relator in a whole bunch of  6 these cases, including the one you're probably  7 noticed on.</p> <p>8 You've spent a lot of time  9 testifying about average manufacturers' price in  10 response to both Mr. Cook's and Mr. Escobar's  11 questions earlier.</p> <p>12 Do you recall that?</p> <p>13 A. Yes.</p> <p>14 Q. Now, they asked you about average  15 manufacturers' price, but do you also recall a  16 term "best price"?</p> <p>17 A. Yes.</p> <p>18 Q. As used in the Medicaid rebate  19 statute?</p> <p>20 A. That's correct. Yes.</p> <p>21 Q. And that would be OBRA '90.  22 Correct?</p>	<p>1 obligations under the Medicaid rebate program and  2 under their Medicaid rebate agreements --</p> <p>3 MR. ESCOBAR: Objection to the  4 form.</p> <p>5 Q. -- with HHS?</p> <p>6 A. Again, it was my understanding that  7 manufacturers provided average manufacturer's  8 price and best price.</p> <p>9 Q. And best price, okay. Now, and was  10 it also your understanding that that information  11 had to be maintained as confidential by -- with  12 the Health Care Financing Administration?</p> <p>13 Correct?</p> <p>14 A. By the unit in the Health Care  15 Financing Administration that administered the  16 rebate program.</p> <p>17 Q. Other than specific patient  18 information, can you think of any information that  19 was held to a higher degree of confidentiality by  20 HCFA during your term there?</p> <p>21 MR. ESCOBAR: Objection to the  22 form.</p>

76 (Pages 582 to 585)

Henderson Legal Services  
202-220-4158

320d321f-596a-4e1f-8444-2c4e6f42d4ae

Vladeck, Ph.D., Bruce C. - Vol. II

June 21, 2007

New York, NY

Page 586	Page 588
<p>1        A. No, I think the restrictions on the 2 information received under the rebate program were 3 quite extraordinary relative to other information 4 we received.</p> <p>5        Q. Now, you testified a lot about -- 6 about your knowledge or at least your impressions 7 as to some of the political issues that were 8 affecting your job and your -- and your agency's 9 ability to make policy.</p> <p>10       Do you remember that?</p> <p>11       A. Yes.</p> <p>12       Q. Well, along that line, when it came 13 to this confidentiality of information, was it -- 14 do you have a recollection as to what group or 15 entity wanted to keep this information so 16 confidential?</p> <p>17       MR. ESCOBAR: Objection to the form 18 of the question.</p> <p>19       A. Again I have no firsthand 20 knowledge, but my understanding was that in the 21 legislative process that produced OBRA '90 the 22 manufacturers were quite insistent on maintenance</p>	<p>1        MR. ESCOBAR: It's also leading. 2        MR. BREEN: Counsel, I'm going to 3 tell you something right now. I did not do 4 anything when you were inquiring of the witness 5 other than object on the basis of form. I made no 6 speaking objections, and I don't expect any when 7 I'm questioning the witness.</p> <p>8        Q. Now, let's go back.</p> <p>9        MR. ESCOBAR: Mr. Breen, you're 10 mischaracterizing the rebate agreement 11 intentionally, and I assume that you really don't 12 want to do that, so I'm trying to help you --</p> <p>13       MR. BREEN: I understand that, 14 counsel.</p> <p>15       MS. BROOKER: I would like to make 16 an objection on behalf of the United States, Mr. 17 Escobar. Much of your examination, particularly 18 in this area, was very misleading. I made none of 19 those speaking objections on the record; I merely 20 objected to form. It is improper that you make 21 any speaking objections. You say "objection, 22 form," and we all agree here that all of your</p>
Page 587	Page 589
<p>1 of confidentiality associated with the mandatory 2 reporting requirements under the rebate 3 provisions.</p> <p>4        Q. Are you aware of any patient groups 5 that wanted this information to be kept 6 confidential?</p> <p>7        MR. ESCOBAR: Objection to the 8 form.</p> <p>9        A. Again, this is second to third- 10 hand, and the only -- the impression that I've 11 reported all I know.</p> <p>12       Q. Okay. That it was the drug 13 manufacturers that wanted to keep this information 14 at an unprecedented level of confidentiality by 15 HCFA.</p> <p>16       MR. ESCOBAR: Objection to the 17 form, and you're mischaracterizing the rebate 18 agreement signed by the government on behalf of 19 the states.</p> <p>20       Q. Is that correct, Dr. Vladeck?</p> <p>21       A. Is what correct?</p> <p>22       Q. All right. Let's go back.</p>	<p>1 objections are preserved.</p> <p>2        MR. BREEN: All right. Now, let's 3 move on. The day is getting old very quickly, and 4 we all want to get finished.</p> <p>5        Q. Let's just go back to this 6 confidentiality requirement for information 7 provided to the Health Care Financing 8 Administration by drug companies in connection 9 with the requirements of OBRA '90 and the Medicaid 10 drug rebate program. Okay? I'm just focusing on 11 that right now.</p> <p>12       A. Okay.</p> <p>13       Q. Did you ever, in the entire time 14 you were with HCFA, either directly or hear about 15 a drug company encouraging HCFA to use its AMP 16 information and best-price information to set 17 reimbursement for its drugs either by the Medicare 18 program or the Medicaid program?</p> <p>19       MR. ESCOBAR: Objection to the 20 form.</p> <p>21       A. No.</p> <p>22       Q. So, when HCFA established these</p>

77 (Pages 586 to 589)

Henderson Legal Services  
202-220-4158

Vladeck, Ph.D., Bruce C. - Vol. II

June 21, 2007

New York, NY

Page 590	Page 592
<p>1 unprecedented protections for the drug company  2 pricing information, who did you believe HCFA was  3 trying to protect?</p> <p>4 MR. ESCOBAR: Objection to the  5 form.</p> <p>6 A. Again, I don't believe we were  7 particularly trying to protect anyone. We were  8 interpreting the statute as it was explained to us  9 and interpreted to us, which required that. And,  10 again, second or thirdhand, it was my  11 understanding that it was at the behest of the  12 manufacturers that this level of confidentiality  13 was required.</p> <p>14 Q. Okay. Now, you testified earlier -  15 - you were asked a bunch of questions about  16 whether the state Medicaid programs were provided  17 with AMP information directly by HCFA.</p> <p>18 Do you recall those questions  19 today?</p> <p>20 MR. ESCOBAR: Objection to the  21 form.</p> <p>22 A. Yes.</p>	<p>1 that some of that information would be shared as  2 part of the rebate process, but that's a second-  3 or third-hand understanding.</p> <p>4 Q. Okay. How about best-price  5 information? Was that ever communicated to a  6 state?</p> <p>7 A. I don't know.</p> <p>8 Q. Okay. Now, if you could pull up  9 Exhibit -- Exhibit Dey 022, this chart that Mr.  10 Escobar spent a lot of time asking you about.  11 Do you have that?</p> <p>12 A. Yes, I have it.</p> <p>13 Q. And just generally questions about  14 whether it was your understanding that these state  15 formulas were appropriate or allowed under the  16 applicable laws and regulations.</p> <p>17 Do you recall that?</p> <p>18 MR. ESCOBAR: Objection to the  19 form.</p> <p>20 A. Yes.</p> <p>21 Q. Okay. Now, to the extent you  22 answered any questions about Exhibit Dey 022, were</p>
Page 591	Page 593
<p>1 Q. Okay. And sitting right now, do  2 you have a present recollection of HCFA actually  3 providing AMP information to any state?</p> <p>4 A. I had no firsthand exposure to any  5 such transactions at any time.</p> <p>6 Q. And as a matter of fact, has  7 anybody ever -- let me just ask you this question:  8 Has anybody ever directly told you that HCFA, on  9 any occasion, ever provided AMP information to any  10 state?</p> <p>11 A. Not that I'm aware of.</p> <p>12 Q. So, if you were to testify earlier  13 today about the HCFA giving up state AMP  14 information, was that -- were you speculating or  15 were you -- what were you basing that testimony  16 on?</p> <p>17 MR. ESCOBAR: Objection to the  18 form, and you're mischaracterizing his testimony.</p> <p>19 A. If I testified to the contrary I  20 was in error. My -- I have no firsthand knowledge  21 of HCFA ever directly communicating AMP  22 information to a state. It was my understanding</p>	<p>1 any of your answers based upon your direct  2 knowledge that this exhibit correctly reflects the  3 state reimbursement formulas?</p> <p>4 MR. ESCOBAR: Objection to the  5 form.</p> <p>6 A. I would state that in answering  7 questions based on this exhibit I assumed it was  8 accurate.</p> <p>9 Q. You assumed it was accurate, okay.  10 So, for example, where Mr. Escobar's questions  11 represented that New York only pays based upon  12 AWP, do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Were your answers based upon your  15 own knowledge of the New York reimbursement  16 requirements or was it based upon just your  17 assumption that this chart is correct?</p> <p>18 MR. ESCOBAR: Objection to the  19 form.</p> <p>20 A. Actually, the New York instance  21 would be the only one in which I had any  22 independent knowledge, or one of the few in which</p>

78 (Pages 590 to 593)

Henderson Legal Services  
202-220-4158

320d321f-596a-4e1f-8444-2c4e6f42d4ae

Vladeck, Ph.D., Bruce C. - Vol. II

June 21, 2007

New York, NY

Page 594	Page 596
<p>1 I had independent knowledge, because of the recent  2 discussions in the last years of Medicaid  3 reimbursement for prescription drugs in New York.  4 And while I don't remember  5 specifically, I do remember that New York has long  6 had a reputation of being a disproportionately  7 generous payer for Medicaid drugs.</p> <p>8 Q. Now, with respect to each of these  9 reimbursement formulas on Exhibit Dey 022 which  10 are based upon WAC or AWP, is it -- well, have you  11 ever had an understanding that any state's  12 reimbursement formula that was approved by HHS  13 allowed it to pay more than average wholesale  14 price --</p> <p>15 MR. ESCOBAR: Objection --</p> <p>16 Q. -- for the ingredient cost?</p> <p>17 MR. ESCOBAR: Objection to the  18 form.</p> <p>19 A. Not -- not subsequent to the  20 implementation of OBRA '90.</p> <p>21 Q. And how about, are you aware of any  22 state reimbursement formula that had been approved</p>	<p>1 Q. All right. Now, looking at Florida  2 again where you have WAC plus 7 percent, when you  3 were the HCFA administrator, did any  4 representative of Dey Laboratories, Mr. Escobar's  5 client, one of them, ever inform you, or anybody  6 else to your knowledge, that in May of 1995 Dey  7 Laboratories elected to materially inflate their  8 WAC report for albuterol in order to build in a  9 bigger reimbursement spread than their competitor,  10 Warrick, who is represented by Mr. McDonald here  11 today?</p> <p>12 MR. ESCOBAR: Objection to the  13 form.</p> <p>14 A. I would say that I can be  15 reasonably certain that I never had such a  16 conversation remotely like that with any drug  17 manufacturer, and I would be surprised if any of  18 my colleagues did.</p> <p>19 Q. If you look at Exhibit Dey 023,  20 which was the Dey rebate agreement, and go to Page  21 122, the signature page, do you see who it's  22 signed by for Dey Laboratories?</p>
Page 595	Page 597
<p>1 by HHS that permits a state to pay less than --  2 strike that.</p> <p>3 -- that permits a state to pay --  4 let me restate the question then.</p> <p>5 If you look -- look at Florida on  6 the chart.</p> <p>7 Do you see that?</p> <p>8 A. I do.</p> <p>9 Q. And according to this, it says that  10 its ingredient reimbursement basis is WAC plus 7  11 percent. Do you see that?</p> <p>12 A. I do.</p> <p>13 Q. Now, what is your understanding of  14 what WAC is?</p> <p>15 A. Again, my understanding of WAC is  16 it would be the actual market invoice costs paid  17 by pharmacies to acquire the drugs.</p> <p>18 Q. Okay. Now, by pharmacies or by the  19 wholesaler?</p> <p>20 A. No, I believe it would be -- my  21 understanding was that it would be by the  22 pharmacy.</p>	<p>1 A. Well, I can't quite read the  2 handwriting. It appears to be an R. Mozak.</p> <p>3 Q. Mozak. And I'll represent to you  4 that I believe that's Robert Mozak. And you see  5 VP of marketing was his title?</p> <p>6 A. I see that.</p> <p>7 Q. And you see purportedly he signed  8 it on February 28th, 1991?</p> <p>9 A. I see that.</p> <p>10 Q. Did Mr. Mozak or anybody else at  11 Dey Laboratories ever advise you that in February  12 of 1992 Mr. Mozak prepared a marketing plan that  13 said that Dey was going to market its drugs based  14 upon its reported prices and its influence over  15 Medicaid and Medicare reimbursement?</p> <p>16 MR. ESCOBAR: Objection to the  17 form, and you're misrepresenting the evidence.</p> <p>18 MR. BREEN: I absolutely am not  19 misrepresenting the evidence, counselor.</p> <p>20 MR. ESCOBAR: You are.</p> <p>21 MR. BREEN: Be that as it may,  22 we'll take that up later.</p>

Vladeck, Ph.D., Bruce C. - Vol. II

June 21, 2007

New York, NY

Page 598	Page 600
<p>1 Q. I'm asking you if anybody ever 2 informed you of that or anything -- anything like 3 that.</p> <p>4 A. No, I certainly would have 5 remembered such a conversation or communication if 6 I had it.</p> <p>7 Q. Now, did anybody ever communicate 8 to you as the HCFA administrator, or anyone else 9 at HCFA to your knowledge, that Warrick reported 10 prices that were maintained in a separate database 11 from its actual transaction prices that had no 12 relation to its actual transaction costs 13 whatsoever when it reported prices that it knew 14 would be used for Medicare and Medicaid 15 reimbursement?</p> <p>16 MR. MC DONALD: Object to the form. 17 That's a gross misstatement of facts.</p> <p>18 MR. BREEN: I do not believe it is, 19 counsel.</p> <p>20 Q. Did anybody ever inform you that 21 about Warrick?</p> <p>22 MR. MC DONALD: Object to the form.</p>	<p>1 Q. Bristol-Myers. Did you remember 2 questions about the drug VePesid?</p> <p>3 A. Yes.</p> <p>4 Q. And were you aware -- and that was 5 included in the Ven-A-Care letter of October 2nd 6 of 1996. Correct?</p> <p>7 A. That's my understanding. Yes, it 8 was.</p> <p>9 Q. And was it your understanding that 10 Bristol-Myers was the brand manufacturer for 11 VePesid?</p> <p>12 A. Yes.</p> <p>13 Q. And that's the etoposide brand. 14 Correct?</p> <p>15 A. Whatever the document said or I was 16 told.</p> <p>17 Q. Now, what was your understanding 18 the entire time as to -- that you were HCFA 19 administrator as to the relationship of brand 20 products to their AWP versus the actual prices 21 available in the marketplace?</p> <p>22 A. Again, as I think I've testified on</p>
Page 599	Page 601
<p>1 A. Perhaps I can finesse the issue by 2 saying that, with all due respect, I don't know 3 that I ever heard of Warrick during the course of 4 my tenure.</p> <p>5 MS. BROOKER: I object on the 6 record to the speaking objections by defense 7 counsel here today.</p> <p>8 MR. MC DONALD: I have a duty as 9 counsel to be sure that there's not 10 misrepresentations made to this witness. He's an 11 officer of the court and he should not make gross 12 misrepresentations of fact, and I will make my 13 appropriate objections.</p> <p>14 Thank you very much.</p> <p>15 MS. BROOKER: Those are speaking 16 objections, and I did not make those speaking 17 objections to the gross misrepresentations made by 18 Mr. Escobar today.</p> <p>19 MR. ESCOBAR: That's outrageous. 20 That really is outrageous.</p> <p>21 MR. BREEN: Let me just finish this 22 up.</p>	<p>1 a number of occasions both on the prior day and 2 today, my understanding was that there was a very 3 broad range of prices in the marketplace but that 4 for brand name products on average the difference 5 between actual transaction price and the price as 6 reported in the Red Book would be in the range of 7 15 to 20 percent.</p> <p>8 Q. Did anybody tell you when you were 9 at HCFA, or anybody to your knowledge at HCFA 10 that Bristol priced its VePesid product to compete 11 with generics and created a spread similar to the 12 generics?</p> <p>13 MR. EDWARDS: Objection.</p> <p>14 A. I don't believe I ever had a 15 conversation about the specific pricing of any 16 drug other than Lupron in -- in all the time I was 17 HCFA administrator.</p> <p>18 Q. Now, going back to Exhibit Dey 022, 19 if I remember your testimony correctly there were 20 times when you got to HCFA you -- it was your 21 understanding HCFA could not change the formula 22 for Medicaid reimbursement for a certain period of</p>

80 (Pages 598 to 601)

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Vladeck, Ph.D., Bruce C. - Vol. II

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Page 602	Page 604
<p>1 time. Correct?</p> <p>2 MR. ESCOBAR: Objection to the</p> <p>3 form. It mischaracterizes the testimony.</p> <p>4 Q. Is that correct?</p> <p>5 A. My understanding was that that</p> <p>6 applied to the dispensing fees.</p> <p>7 Q. Dispense fees. Okay. Thank you</p> <p>8 for correcting me.</p> <p>9 And then later on there was a time</p> <p>10 -- or are you aware that after you left HCFA your</p> <p>11 successor for a limited period of time was told by</p> <p>12 Congress not to change the reimbursement formula</p> <p>13 for Medicare?</p> <p>14 A. For Medicare?</p> <p>15 Q. For Medicare.</p> <p>16 A. Yes. There were very extensive</p> <p>17 back-and-forth on the Medicare drug pricing.</p> <p>18 Q. Okay. Now let's go to Exhibit Dey</p> <p>19 022.</p> <p>20 To the extent that any drug</p> <p>21 manufacturer reported inflated pricing information</p> <p>22 that -- or strike that.</p>	<p>1 that Abbott Laboratories was manufacturing a</p> <p>2 generic Vancomycin and reported prices that caused</p> <p>3 AWP to be reported higher than Lilly's brand?</p> <p>4 MR. COOK: Objection.</p> <p>5 A. I don't -- I don't believe I was</p> <p>6 ever aware of any pricing information having to do</p> <p>7 with Vancomycin.</p> <p>8 Q. Okay. Now, these spreads that have</p> <p>9 been talked about and you've seen them in the Ven-</p> <p>10 A-Care letter and there's been discussions here</p> <p>11 today and on your first day, when you were HCFA</p> <p>12 administrator did you have an understanding that</p> <p>13 the Department of Justice and the HHS office and</p> <p>14 Inspector General were conducting the necessary</p> <p>15 investigations to find out if, and if so, why,</p> <p>16 prices were being reported at inflated levels that</p> <p>17 were being used for drug reimbursement?</p> <p>18 MR. ESCOBAR: Objection to the</p> <p>19 form.</p> <p>20 MS. BROOKER: Objection.</p> <p>21 You know, I ask you to be mindful</p> <p>22 not to disclose any deliberative predecisional</p>
Page 603	Page 605
<p>1 To the extent that any drug</p> <p>2 manufacturer was reporting pricing information</p> <p>3 that led to the publishing of their AWPs or led to</p> <p>4 these WAC reports that are being -- that are</p> <p>5 referred to here on this exhibit, to the extent</p> <p>6 that the manufacturer would report a lower price,</p> <p>7 either AWP for AWP reimbursement or WAC for WAC</p> <p>8 reimbursement, would that result in lower</p> <p>9 reimbursement for the ingredient cost?</p> <p>10 MR. ESCOBAR: Objection to the</p> <p>11 form.</p> <p>12 Q. Under the Medicaid program?</p> <p>13 MR. ESCOBAR: Same objection.</p> <p>14 A. Yes.</p> <p>15 Q. Now, the whole time you were at</p> <p>16 HCFA, did either you or anybody else ever inform a</p> <p>17 drug manufacturer that it should not lower its</p> <p>18 price reports if appropriate?</p> <p>19 MR. COOK: Objection.</p> <p>20 A. Certainly not that I'm aware.</p> <p>21 Q. Okay. Now, while you were at HCFA</p> <p>22 did you or anybody to your knowledge become aware</p>	<p>1 conversations.</p> <p>2 MR. BREEN: I'll restate the</p> <p>3 question. I don't intend to cause that.</p> <p>4 As a matter of fact, I'll withdraw</p> <p>5 that question.</p> <p>6 Q. Let me ask this question: Did you</p> <p>7 ever believe that it was your responsibility or</p> <p>8 HCFA's responsibility to investigate drug company</p> <p>9 conduct with respect to reporting prices that were</p> <p>10 being used for Medicaid and Medicare</p> <p>11 reimbursement?</p> <p>12 MR. ESCOBAR: Objection to the</p> <p>13 form.</p> <p>14 A. I believed it was our</p> <p>15 responsibility, when we became aware of any</p> <p>16 potential fraud or abuse involving our programs,</p> <p>17 to alert the Inspector General and in some</p> <p>18 instances the Department of Justice.</p> <p>19 Again, other than the noted copies</p> <p>20 on that Ven-A-Care letter, I don't recall ever</p> <p>21 having been aware of that -- of the applicability</p> <p>22 of that general policy to the issue of drug</p>